

1315415

# INVENTION IN THE UNITED STATES OF AMERICA

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*April 28, 2005*

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FILING DATE.

APPLICATION NUMBER: 60/563,237

FILING DATE: *April 16, 2004*

RELATED PCT APPLICATION NUMBER: PCT/US05/12274



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## PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 CFR 1.53 (b)(2).

16569 U.S.P.T.O.

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00746  
60/563237

Docket Number	D-3150P			Type a plus sign (+) inside this box -	+
INVENTOR(s)/APPLICANT(s)					
LAST NAME	FIRST NAME	MIDDLE INITIAL	RESIDENCE (CITY AND EITHER STATE OR FOREIGN COUNTRY)		
CHAMPION	MARY	J.	HUNTINGTON BEACH, CALIFORNIA		
TITLE OF THE INVENTION (280 characters max)					
<b>KIT AND METHOD FOR TREATING HOT FLASHES ASSOCIATED WITH MENOPAUSE</b>					
CORRESPONDENCE ADDRESS					
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STATE	CA	ZIP CODE	92618	COUNTRY	USA
ENCLOSED APPLICATION PARTS (check all that apply)					
X	Specification	Number of Pages	17	X	Small Entity Statement - YES
X	Drawing(s)	Number of Sheets	1	Other(specify)	
METHOD OF PAYMENT (check one)					
X	A check or money order is enclosed to cover the Provisional filing fee				PROVISIONAL FILING FEE AMOUNT (\$)
	The Commissioner is hereby authorized to charge filing fees and credit deposit Account Number:				\$80.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

 No. Yes, the name of the U.S. Government agency and the Government contract number are: \_\_\_\_\_

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Frank J. Uxa, Reg. No. 25,612, Donald E. Stout, Reg. No. 34,493; Robert D. Buyan, Reg. No. 32,460; Kenton R. Mullins, Reg. No. 36,331; Jo Anne M. Ybaben, Reg. No. 42,243, Linda Allyson Fox, Reg. No. 38,883, Greg S. Hollrigel, Reg. No. 45,374, and Louise S. Heim, Reg. No. 32,337.

Respectfully submitted,

SIGNATURE

Frank J. Uxa, Reg. #25,612

Date

4/16/04

 Additional inventors are being named on separately numbered sheets attached hereto

**PROVISIONAL APPLICATION FILING ONLY**  
SEND TO: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450

D-3150P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
PATENT

In re application of:

CHAMPION

) Group Art Unit: N/A

Serial No. N/A

) Examiner: N/A

Dated: Submitted herewith

)

For: KIT AND METHOD FOR TREATING  
HOT FLASHES ASSOCIATED  
WITH MENOPAUSE

)  
)  
)

ATTN: MAIL STOP PROVISIONAL  
PATENT APPLICATION

Express Mail Mailing Label No. EV 446208161 US

Date of Deposit: April 16, 2004

I hereby certify that the following documents as identified below are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and are addressed to the Commissioner for Patents, Mail Stop Provisional Application, P.O. Box 1450, Alexandria, VA 22313-1450:

1. Provisional Application Cover Sheet;
2. Application Data Sheet
3. Application (17 pages);
4. 1 Sheet of Drawing (informal)
5. Return receipt postcard; and
6. Check for \$80.00

The 6 above-identified documents are enclosed herewith.

Respectfully submitted,

  
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DOCKET NO.: D-3150P

THE ENCLOSED PROVISIONAL PATENT APPLICATION OF MARY J.  
CHAMPION IS BEING FILED IN ACCORDANCE WITH SECTION 37 CFR  
1.10 BY EXPRESS MAIL AND SHOULD BE ACCORDED A FILING DATE  
OF:

April 16, 2004

SEE THE EXPRESS MAIL CERTIFICATE ATTACHED TO THE APPLICATION.

KIT AND METHOD FOR TREATING HOT FLASHES ASSOCIATED WITH  
MENOPAUSE

BACKGROUND

5

This invention relates generally to treating one or more symptoms associated with menopause in a menopausal woman. In particular, the invention relates to a kit and method for treating hot flashes in a menopausal woman.

10

Typically, hot flashes associated with menopause have been treated with hormones. However, hormone therapy may be associated with numerous side effects. Thus, hormone therapy is not often recommended for the treatment of hot 15 flashes in menopausal women. Alternatives in treating hot flashes are needed.

20

U.S. Patent No. 4,900,554 discloses an adhesive device for application to body tissue to provide sustained drug release or to protect a body tissue, the device having an adhesive layer and a backing layer positioned over one side of the adhesive layer. The adhesive layer includes one or more acrylic acid polymers having adhesive properties upon dissolution or swelling in water, and at least one water 25 insoluble cellulose derivative. The backing layer is water insoluble or sparingly water soluble.

30

U.S. Patent No. 5,780,047 discloses a patch that comprises a water-soluble adhesive sheet, and a water-soluble protective material laminated thereon. The patch can be applied to the skin so as to exhibit warm-bathing effects on the application site.

35

U.S. Patent Nos. 6,224,899; 6,228,376; and 6,524,612 disclose an adhesive cooling gel composition which contains a large amount of water and which provides a cooling effect

and/or coolness-preserving effect, and a process for preparing the same. The composition comprises a polyacrylic acid compound, a polyvalent metal component and water, wherein the content of water is 75 to 95% by weight based on  
5 the cooling composition. Also disclosed are an adhesive cooling composition shaped into a sheet, and a process for preparing the adhesive cooling composition, the process being selected from processes given below in (1) to (3), each process including a step of mixing and dissolving the  
10 components of the composition and a deaerating step: (1) a process wherein an aqueous solution is deaerated and then the other components of the composition are mixed and/or dissolved; (2) a process wherein while an aqueous solution is deaerated, the other components of the composition are  
15 mixed and/or dissolved; or (3) a process wherein after the other components of the composition are mixed and/or dissolved, the obtained solution is deaerated.

U.S. Patent No. 5,956,963 discloses a wrist cooler that  
20 offers relief for hot flash symptoms of menopause and body overheating. The cooler includes chemical cooling pellets that remain in a solid state until broken. A woman experiencing symptoms such as menopausal hot flashes carries the cooler in her purse. When hot flashes occur, the cooler  
25 is removed from her purse, the pellets are broken and the cooler is slid onto her wrist. Once the flashes have subsided, the cooler is discarded. The cooler is easily transportable and provides for immediate relief, as there are no reusable cooling elements to be frozen or chilled.  
30

U.S. Patent Publication No. 2003/0176904 discloses a self-adhering cotton fabric cold strip that is to be worn as a wrist band, or an ankle band. The self-adhering cotton fabric cold strip has an envelope defining a sealed cold  
35 strip volume. A cooling gelatinous material is positioned in the cold strip volume. A bandage sheet is fixed to the

envelope. The bandage sheet defines a bandage adhesive for temporary adhesion of the cold strip to the skin surface of a user. The self-adhesive envelope contains a cooling gelatinous material which reduces the body temperature. The  
5 reduction of the body temperature brings relief that is convenient, portable, and lasts for hours. The cold strip is to be worn for a period of hours and is then disposed and replaced with another cold strip. The self-adhering cotton fabric cold strip will be produced with different colors of  
10 cloth.

In view of the disadvantages of hormone therapy, and the shortcomings associated with wrist or ankle cooling devices, such as the noticeable presence of the devices,  
15 improved treatments are needed to control and reduce hot flash symptoms in menopausal women.

#### SUMMARY

20 The present invention is generally directed to a non-hormonal treatment of hot flashes. A kit and method are described which involve placing a cooling device on an inconspicuous location, preferably on a torso and more preferably on an upper portion of a back of a woman who is  
25 experiencing a hot flash or who is prone to experiencing a hot flash. Although the exemplary embodiment of the invention is directed to placing the cooling device on the back of a woman, the cooling device may be placed at any hot flash origin site, or the site where the hot flash is felt  
30 first. Such origin sites can be any place on the body. For example, the origin site may be on the upper portion of a woman's body or a lower portion of a woman's body. In certain situations, the origin site is any location other than the wrists, ankles, or chest. In certain situations,  
35 the origin site is a location on a woman's stomach, in

proximity to the elbow of the woman's arms, on the woman's neck, or on the woman's back.

In one embodiment, a kit for treating hot flashes  
5 associated with menopause in a woman comprises one or more cooling devices; and instructions for using the cooling device or devices. The instructions include directions to place the cooling device on the skin of a woman at a hot flash origin site, such as a location on her back, such as  
10 between her shoulder blades, when a hot flash begins.

In another embodiment, a method for treating hot flashes comprises providing at least one cooling device; and instructing a woman to place the at least one cooling device  
15 at a hot flash origin site, such as a location on her back, such as between the shoulder blades, when the hot flash begins.

Each and every feature described herein, and each and  
20 every combination of two or more of such features, is included within the scope of the present invention provided that the features included in such a combination are not mutually inconsistent. In addition, any feature or combination of features may be specifically excluded from  
25 any embodiment of the present invention.

Additional advantages and aspects of the present invention are apparent in the following detailed description, drawings, and claims.

30

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic illustration of a kit for treating hot flashes.

35

FIG. 2 is a top plan view of a cooling device provided in the kit of FIG. 1.

5 FIG. 3 is a bottom plan view of the cooling device of FIG. 2.

FIG. 4 is a side view along line 4-4 of FIG. 3.

10 FIG. 5 is an illustration of two cooling devices located on the back of a menopausal woman.

#### DETAILED DESCRIPTION

A kit for treating hot flashes associated with 15 menopause in a woman comprises at least one cooling device; and instructions for using the cooling device. The instructions include directions to place the at least one cooling device on the skin of a woman at a hot flash origin site when the woman experiences a hot flash, such as when a 20 hot flash begins.

Although the exemplary embodiment of the invention is directed to placing the cooling device on the back of a woman, the cooling device may be placed on any region of the 25 woman's body, for example, at any hot flash origin site, or the site where the hot flash is felt first. Advantageously, the cooling device is placed on a region of the woman's body that is above the ankles and wrists, for example, at or above the knees and elbows. In one embodiment, the cooling 30 device is placed on the woman's torso.

In one embodiment, the cooling device is placed on an inconspicuous region of the woman's body, that is a region of the woman's body that can carry the cooling device 35 without the cooling device being apparent to others. Since the upper portion of a woman's chest is often exposed even

when the woman is clothed, in one embodiment, the region of the woman's body which the cooling device is placed is other than the upper portion of the woman's chest.

Hot flash origin sites can be any place on the body.  
5 For example, the origin site may be on the upper portion of a woman's body or a lower portion of a woman's body. In certain situations, the origin site is any location other than the wrists, ankles, or chest. In certain situations, the origin site is a location on a woman's stomach, in  
10 proximity to the elbow of the woman's arms, on the woman's neck, or on the woman's back.

Typically, the cooling device is placed on the woman's body, for example, on the hot flash origin site, as soon as  
15 possible after a hot flash begins, such as within about five minutes from when a hot flash begins, for example, within about two minutes from when a hot flash begins.

In reference to the accompanying drawings, which are  
20 provided as example of one embodiment of the present invention, a kit 10 comprising a plurality of cooling devices 12, and instructions for use 14 is illustrated in FIG. 1. The kit 10 is in the form of a sealed package 16. Although two cooling devices 12 are illustrated in the kit  
25 10, the kit 10 may include only one cooling device 12, or more than two cooling devices 12. In addition, each cooling device 12 may be provided in individual sealed packages provided with the sealed package 16.

30 The cooling device 12 of the kit 10 may be any suitable device configured to cool the skin of a woman experiencing a hot flash. For example, the cooling device 12 may be a device that can be placed in a freezer or refrigerator, and the like, and then can be removed and placed on the skin at  
35 a cooled temperature (e.g., a temperature below room temperature, such as below about seventy degrees

Fahrenheit). One example of such a cooling device is an "ice-pack". Or, the cooling device 12 may be a device configured to cool the woman's skin by removing heat from the woman's skin, such as by evaporation.

5

One example of a cooling device 12 is illustrated in FIG. 2. As illustrated, the cooling device 12 of FIG. 2 is symmetrical about an axis A. The cooling device 12 includes a first portion 22 and a second portion 24. The second portion 24 extends from the first portion 22. The first portion 22 has a width 22W, and the second portion 24 has a width 24W. The width 22W and the width 24W are substantially perpendicular to the axis A. The width 24W is illustrated as being smaller than the width 22W. The cooling device 12 is generally shaped as a T.

As shown in FIG. 3, the cooling device 12 comprises a cooling component 18 coupled to a substrate 20. The substrate 20 typically comprises a gas-permeable material, such as a natural or synthetic fiber material. In certain cooling devices, the substrate 20 consists comprises, consists essentially of, or consists of a cotton fiber sheet. The cooling component 18 is surrounded by a border 26 of the substrate 20. The border 26 is substantially free of the cooling component 18. In certain embodiments, the border 26 may include one or more adhesive regions effective in facilitating adhesion of the cooling device 12 on the woman's skin. The adhesive regions may include the same material of the cooling component 18, or may include other adhesive materials, such as topically acceptable glues, and the like.

FIG. 4 illustrates the thickness of the cooling device 12. The thickness of the cooling device 12 is determined by the thickness of the substrate 20 and the cooling component 18. Preferably, the thickness of the cooling device 12

relatively small so that the cooling device 12 is not substantially visible through a woman's clothing when the device is placed on the woman's skin.

5       The cooling device 12 of the kit 10 may be an adhesive patch. The patch should be tacky or sticky enough to permit a woman to wear the cooling device on her skin for extended periods of time, if desired. For example, the patch may adhere to the woman's skin for more than one minute, and may  
10      adhere to the woman's skin for six hours or more. In addition, the patch may be readhered to the skin after being used, if desired.

15      In one embodiment, the adhesive patch comprises, consists essentially of, or consists of a water-containing gel. The gel may be coupled to a gas-permeable substrate, such as a fibrous material. For example, the adhesive patch may consist essentially of a water-containing gel coupled to a cotton fiber sheet. The water containing gel may comprise  
20      a polyacrylic acid component. The water containing gel may have a water content from about 75% to about 95% by weight of the gel. One example of a cooling device 12 which comprises a water-containing gel coupled to a gas permeable substrate is disclosed in U.S. Patent Nos. 6,224,899; 25 6,228,376, and 6,524,612, and which is publicly available under the tradename Be Kooool® (Kobayashi Pharmaceutical Co., LTD. Corporation, Japan).

30      The cooling device 12 may be substantially free of a pharmaceutical agent, such as a pharmaceutical agent used in the treatment of menopause symptoms, such as hot flashes.

35      As shown in the drawings, the cooling device 12 is approximately "T-shaped". The cooling device may have a width, such as the width 22W, of about 3 inches, a height of

about 2 inches, and a thickness of about 1/8 of an inch. The width 24W may be about 1 inch.

The instructions 14 of the kit 10 may include  
5 directions to apply the at least one cooling device 12 to the desired region of skin within the first five minutes of feeling a hot flash. Directions may be in the form of words, pictures, and combinations thereof. The instructions 14 may also include directions to apply the at least one  
10 cooling device to a region located between the C3 vertebrae and the T6 vertebrae. While not wishing to be bound by any particular theory or mechanism of action, it has been discovered that placing the cooling device 12 in a region of the upper back between the shoulder blades can substantially  
15 alleviate hot flashes associated with menopause. In certain situations, it has been found that placement of a cooling device 12 at a region in proximity to the cervical and thoracic vertebrae at the onset of a hot flash can effectively prevent the hot flash from spreading throughout  
20 a woman's body.

As shown in FIG. 5, the cooling device 12 is placed in an upper region of a woman's back, such as a region between the woman's shoulder blades.

25           In accordance with the present invention, a method of treating hot flashes associated with menopause comprises providing at least one cooling device, such as the cooling devices disclosed herein; and instructing a woman to place  
30 the at least one cooling device on her skin at a location between her shoulder blades when a hot flash begins. The cooling device or cooling devices may be placed in one or two regions on the upper portion of the woman's back between and up from the shoulder blades. For example, a cooling  
35 device may be placed about four inches up from the shoulder blades and just below the nape of the neck and the spinal

cord protrusions. As understood by persons of ordinary skill in the art, the precise location may vary depending on the size of the individual, the size of the patch, and the origin site of the hot flash. When the cooling device is 5 formed in a "T-shaped" configuration, the cooling device can be placed on the back in an upright configuration or an inverted configuration.

The cooling device can be effectively worn during the 10 day or during the night without causing discomfort to the wearer. During the day, the woman can wear the cooling device under her clothes without being noticed by other people. During the night, the woman can wear the patch to control night sweats and hot flashes.

15 The cooling device is preferably secured to the woman's skin for more than one minute, and potentially for six or more hours. By placing the cooling device on the skin during the onset of a hot flash, the symptoms of the hot 20 flash can be effectively alleviated and prevented from spreading through the body. However, the cooling device 12 may be applied at any time a woman is experience a hot flash. Typically, the cooling device 12 is effective in controlling the hot flash symptoms within about 1 to about 2 25 minutes of contact with the skin.

The kit may be made by placing the cooling device and the instructions in a package, and sealing the package.

30 All references, articles, publications and patents and patent applications cited herein are incorporated by reference in their entireties.

35 While this invention has been described with respect to various specific examples and embodiments, it is to be understood that the invention is not limited thereto and

that it can be variously practiced within the scope of the following claims.

I claim:

1. A kit for treating hot flashes associated with menopause in a woman comprising:
  - at least one cooling device; and
  - instructions for using the at least one cooling device to treat one or more symptoms of a hot flash, the instructions including directions to place the at least one cooling device at a location on the back of the woman who is experiencing a hot flash or who is prone to experiencing a hot flash.
2. The kit of claim 1, comprising a plurality of cooling devices.
3. The kit of claim 1, wherein the at least one cooling device is an adhesive patch.
4. The kit of claim 3, wherein the adhesive patch comprises a water-containing gel coupled to a gas-permeable substrate.
5. The kit of claim 4, wherein the gas-permeable substrate comprises a plurality of fibers.
6. The kit of claim 4, wherein the water containing gel comprises a polyacrylic acid component.
7. The kit of claim 4, wherein the adhesive patch comprises one or more strips located at least partially around the water containing gel, the one or more strips being substantially free of the water-containing gel.
8. The kit of claim 7, wherein the one or more strips include one or more adhesive portions effective in adhering the patch to the skin of the woman.

9. The kit of claim 1, wherein the at least one cooling device is free of a pharmaceutical agent.

10. The kit of claim 1, wherein the instructions include directions to apply the at least one cooling device within the first five minutes of feeling a hot flash.

11. The kit of claim 1, wherein the instructions include direction to apply the at least one cooling device to a location between the shoulder blades of the woman.

12. The kit of claim 1, wherein the instructions include directions to apply the at least one cooling device to a region located between the C3 vertebrae and the T6 vertebrae.

13. The kit of claim 1, further comprising a sealed package, the at least one cooling device provided in the sealed package.

14. A method of treating hot flashes associated with menopause in a woman, comprising:

providing at least one cooling device; and  
instructing a woman to place the at least one cooling device at a location on the back of the woman who is experiencing a hot flash or is prone to experiencing hot flashes.

15. The method of claim 14, comprising providing a plurality of cooling devices.

16. The method of claim 14, wherein the at least one cooling device is an adhesive patch.

16. The method of claim 16, wherein the adhesive patch comprises a water-containing gel coupled to a gas-permeable substrate.

18. The method of claim 17, wherein the gas-permeable substrate comprises a plurality of fibers.

19. The method of claim 17, wherein the water containing gel comprises a polyacrylic acid component.

20. The method of claim 17, wherein the adhesive patch comprises one or more strips located at least partially around the water containing gel, the strips being substantially free of the water-containing gel.

21. The method of claim 20, wherein the one or more strips include one or more adhesive portions effective in adhering the patch to the skin of the woman.

22. The method of claim 14, wherein the at least one cooling device is free of a pharmaceutical agent.

23. The method of claim 14, comprising instructing the woman to apply the at least one cooling device within the first five minutes of feeling a hot flash.

24. The method of claim 14, comprising instructing the woman to apply the at least one cooling device at a location between the shoulder blades of the woman.

25. The method of claim 14, comprising instructing the woman to apply the at least one cooling device to a region located between the C3 vertebrae and the T6 vertebrae.

26. The method of claim 14, further comprising a instructing the woman to remove the patch after the hot flash has subsided.

27. A kit for treating hot flashes associated with menopause in a woman comprising:

at least one cooling device; and

instructions for using the at least one cooling device to treat one or more symptoms of a hot flash, the instructions including directions to place the at least one cooling device at a hot flash origin site of the woman who is experiencing a hot flash or who is prone to experiencing a hot flash.

28. The kit of claim 27, wherein the hot flash origin site is a location selected from the group consisting of the stomach, the neck, an elbow region of an arm, or the back.

29. The kit of claim 28, wherein the elbow region location is located on the inner arm of the woman.

30. The kit of claim 27, wherein the instructions include directions to place the at least one cooling device at the hot flash origin site within about 5 minutes of experiencing a hot flash.

31. A method of treating hot flashes associated with menopause in a woman, comprising:

providing at least one cooling device; and

instructing a woman to place the at least one cooling device at a hot flash origin site of the woman who is experiencing a hot flash or is prone to experiencing hot flashes.

32. The method of claim 31, wherein the hot flash origin site is a location selected from the group consisting

of the stomach, the neck, an elbow region of an arm, or the back.

33. The method of claim 32, wherein the elbow region location is located on the inner arm of the woman.

34. The method of claim 31, comprising instructing the woman to place the at least one cooling device at the hot flash origin site within about 5 minutes of experiencing a hot flash.

## ABSTRACT

A kit for treating hot flashes in a menopausal woman includes one or more cooling devices suitable to be placed on skin, and instructions for applying one or more cooling devices at a hot flash origin site, such as a location on the woman's back, such as between the shoulder blades of the woman when experiencing a hot flash. The cooling device or devices may be provided in a sealed package. The cooling devices may be in the form of an adhesive patch that can adhere to the woman's skin. A method for treating hot flashes includes providing one or more cooling devices, and instructing a woman to place the cooling device or devices on her back between her shoulder blades, for example.

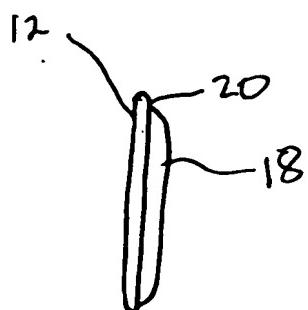
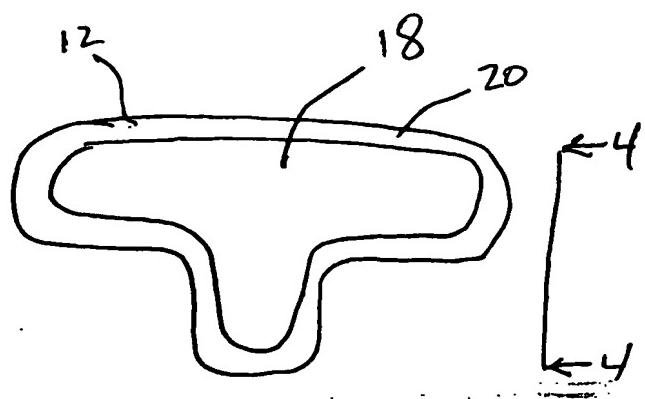
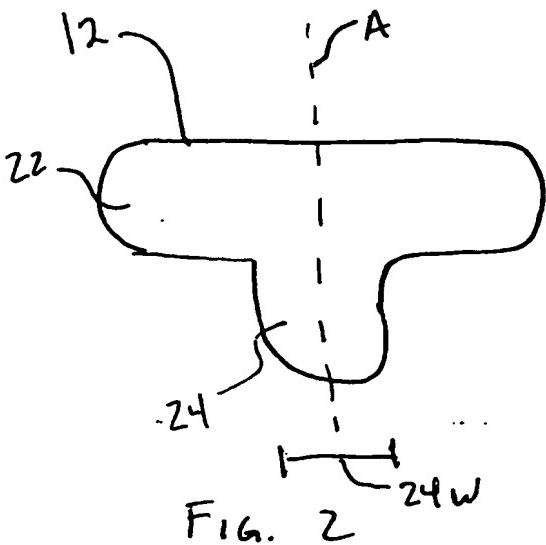
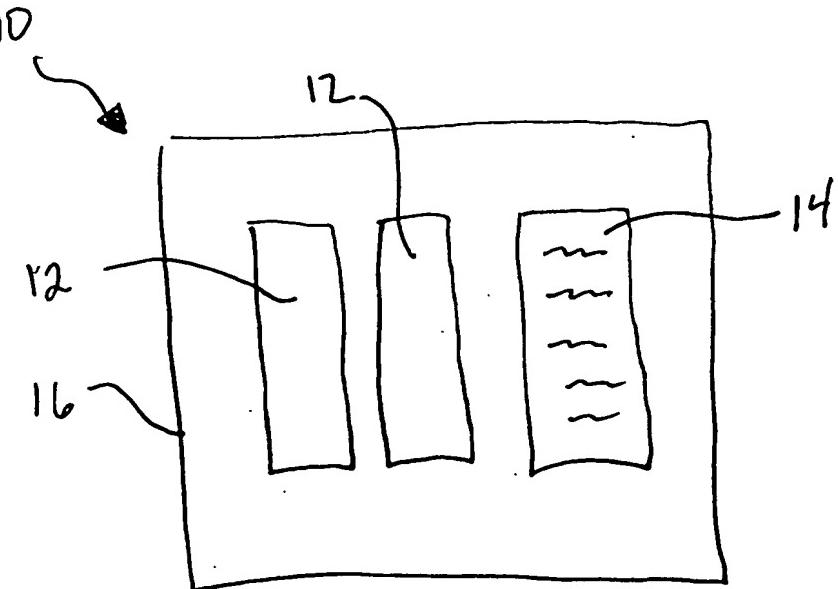


FIG. 4



FIG. 5

## **APPLICATION DATA SHEET**

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### **Application Information**

Title Line One::	Kit and Method for Treating Hot Flashes
Title Line Two::	Associated with Menopause
Total Drawing Sheets::	1
Formal Drawings?::	No
Application Type::	Provisional

## **Representative Information**

Registration Number One::	Frank J. Uxa, Jr.....	25,612
Registration Number Two::	Donald E. Stout.....	34,493
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Registration Number Seven::	Greg S. Hollrigel, Ph. D.....	45,374
Registration Number Eight::	Louise S. Heim.....	32,337

## **Continuity Information**

This application is a::

>Application One::

Filing Date::

## **Assignment Information**

Assignee Name::

Postal Address Line One::

Postal Address Line Two::

City::

State or Province::

Postal or Zip Code::

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